



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
College Park, MD 20740

1570 10 JAN -7 2000

NOV 24

Mr. Robert J. Bernotas
President
Life Source, Inc.
3435 Box Hill Corporate Center Drive
Suite F
Abingdon, Maryland 21009

Dear Mr. Bernotas:

This is in response to your letter of October 21, 2003 to the Food and Drug Administration (FDA) pursuant to 21 U.S.C. 343(r)(6) (section 403(r)(6) of the Federal Food, Drug, and Cosmetic Act (the Act)). Your letter states that the labeling of the product **BioBurn Extreme** will contain the claim "Help to maintain healthy cholesterol."

In the preamble to the January 6, 2000 final rule on structure/function claims (see 65 FR 1000 at 1018), FDA stated that claims about the maintenance of normal cholesterol levels did not necessarily constitute implied disease claims. We stated, however, that because "many people think of cholesterol solely in terms of the negative role of elevated cholesterol in heart disease," in order to avoid implying that the product prevents or treats heart disease, a cholesterol maintenance claim would have to clarify that the product is only for maintenance of cholesterol levels that are already within the normal range. Therefore, because the claim you are making for this product represents that the product is intended to affect blood cholesterol but does not also include a statement about it being intended to affect blood cholesterol that is already in the normal range, it is an implied disease claim.

21 U.S.C. 343(r)(6) makes clear that a statement included in labeling under the authority of that section may not claim to diagnose, mitigate, treat, cure, or prevent a specific disease or class of diseases. The statement that you are making for this product suggests that it is intended to treat, prevent, or mitigate a disease, namely hypercholesterolemia and heart disease. This claim does not meet the requirements of 21 U.S.C. 343(r)(6). This claim suggests that this product is intended for use as a drug within the meaning of 21 U.S.C. 321(g)(1)(B), and that it is subject to regulation under the drug provisions of the Act. If you intend to make claims of this nature, you should contact FDA's Center for Drug Evaluation and Research (CDER), Office of Compliance, HFD-310, Montrose Metro II, 11919 Rockville Pike, Rockville, Maryland 20855.

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Page 2 - Mr. Robert J. Bernotas

Please contact us if we may be of further assistance.

Sincerely yours,

A handwritten signature in black ink, appearing to be 'SJW', written in a cursive style.

Susan J. Walker, M.D.
Director
Division of Dietary Supplement Programs
Office of Nutritional Products, Labeling
and Dietary Supplements
Center for Food Safety
and Applied Nutrition

Copies:

FDA, Center for Drug Evaluation and Research, Office of Compliance, HFD-300

FDA, Office of the Associate Commissioner for Regulatory Affairs, Office of
Enforcement, HFC-200

FDA, Baltimore District Office, Office of Compliance, HFR-MA240



October 21, 2003

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Office of Nutritional Products
Labeling and Dietary Supplements (HFS-800)
Center for Food Safety and Applied Nutrition and Drug Administration
200 C Street, SW
Washington, DC 20204

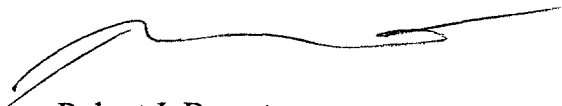
Re: Notification Pursuant to Section 6 of DSHEA and CFR § 101.93 for BioBurn™ Extreme

Gentlemen:

Enclosed please find an original and two (2) copies of the above referenced document.

Very truly yours,

LIFE SOURCE, INC.



Robert J. Bernotas
President

86407

NOTIFICATION PURSUANT TO SECTION 6 OF DSHEA and CFR § 101.93

NOV - 4 2003

This notification is being filed on behalf of Life Source, Inc., which is the manufacturer of the product that bears the statements identified in this notification. Its business address is 3435 Box Hill Corporate Center Drive, Ste F, Abingdon, MD 21009. This notification is being made pursuant to Section 6 of DSHEA and 21 CFR § 101.93. The dietary supplement on whose label and labeling the statements appear is BioBurn™ Extreme.

The text of each structure-function statement for which notification is now being given is:

Statement 1: Fat Loss & Energy Catalyst

Statement 2: Build Lean Muscle

Statement 3: Increase Physical Performance

Statement 4: Stimulate Thermogenesis

Statement 5: Increase Energy and Stamina

Statement 6: Curb Appetite

Statement 7: Improve Body Composition

Statement 8: Help to metabolize fats and carbohydrates

Statement 9: Help to maintain healthy cholesterol

Statement 10: Powerful antioxidant

86407

The following identifies the supplement or dietary ingredients for which statements are made:

Statement Number	Identity of Supplement or Ingredient that is the Subject of the Statement
1	BioBurn Extreme
2	BioBurn Extreme
3	BioBurn Extreme
4	BioBurn Extreme
5	BioBurn Extreme
6	BioBurn Extreme
7	BioBurn Extreme
8	BioBurn Extreme
9	BioBurn Extreme
10	BioBurn Extreme

The following identifies the brand name of the supplement for which statements are made:

Statement Number	Brand Name
1	4 Your Health
2	4 Your Health
3	4 Your Health
4	4 Your Health
5	4 Your Health
6	4 Your Health
7	4 Your Health
8	4 Your Health
9	4 Your Health
10	4 Your Health

I, Robert J. Bernotas, am authorized to certify this Notification on behalf of Life Source, Inc. I certify that the information presented and contained in this Notification is complete and accurate, and that Life Source, Inc. has substantiation that each structure-function statement is truthful and not misleading.

Dated: October 21, 2003

By: 

Title: President

NOTIFICATION PURSUANT TO SECTION 6 OF DSHEA and CFR ^{NOV 14 2008} § 101.93

This notification is being filed on behalf of Life Source, Inc., which is the manufacturer of the product that bears the statements identified in this notification. Its business address is 435 Box Hill Corporate Center Drive, Suite B, Abingdon, MD 21009. This notification is being made pursuant to Section 6 of DSHEA and 21 CFR § 101.93. The dietary supplement on whose label the statements appear is BioBurn™ Extreme.

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